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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,343	03/26/2004	William A. Cook	3433-492	1552

7590 04/18/2007

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EXAMINER	
PREBILIC, PAUL B	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/811,343	COOK ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Information Disclosure Statement

The information disclosure statement filed April 24, 2006 has been considered. The US Patents thereof have been cited on the enclosed PTO-892 because the corresponding US Patents of the PTO-1449 needed to be electronically linked to the present file.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the two provisional applications are listed under heading 35 USC 120 instead of 35 USC 119. Since provisional applications are 35 USC 119(e) documents, they should be placed under the appropriate section of the declaration.

Claim Objections

Claim 27 is objected to because of the following informalities: On line 6 of claim 27, the use of the plural "sources" lacks clear antecedent basis since only one such component was given such a basis. The Examiner will interpret this as the singular form of this term. Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities:

The continuing data as now corrected cannot be correct since priority cannot be based upon a later filed application. Since 60/024,693 filed September 6, 1996 was

filed after parent application 08/916,490 filed August 23, 1996, it cannot be a priority document for the parent application as set forth.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claims 50-54, the language of claim 50 reciting that the peroxy compound is a peracid in confusing and contradictory. In other words, it should be one or the other. For this reason the claim language is considered to be indefinite. Claims 51-54 depend from claim 50 so they are indefinite by incorporating the language thereof.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al (US 5,695,998) alone. Badylak discloses a submucosal tissue source which is first delaminated into tunica muscularis and tunica mucusa (i.e. submucosal

tissue) prior to being disinfected; see column 3, lines 3-44. The present claim language requires a step of separation after the disinfectant treatment rather than before as Badylak discloses. However, the Examiner posits that it would have been obvious to disinfect the tissue both before and after the delamination step as a precaution in order to better ensure sterility of the final implantable product. Furthermore, there is no criticality disclosed in the present specification that shows that it is important to sterilize before delamination. Applicants have not disclosed that changing disinfecting the tissue prior to delamination provides some advantage, is done for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' method to perform equally well because it would result in a submucosal tissue which has been treated with a disinfectant.

Therefore, it would have been an obvious matter of design choice to modify Badylak's method to obtain the invention as specified in the claims.

With regard to claims 28 and 29, Applicants are directed to see column 1, lines 41-59.

With regard to claims 30 and 46, Applicants are directed to see column 8, lines 28-30.

With regard to claim 37, Applicants are directed to see column 7, lines 55-64.

With regard to claims 31-33 and 48-49, Applicants are directed to see Table 1 on column 8 where hydrogen peroxide is the oxidizing agent or peroxy compound. Acetyl peroxide is the organic peroxy compound of claim 33.

With regard to claim 42 and 43, the solutions set forth in Example 2 of Badylak should inherently have the same pH as the claimed solution because they are the same as the claimed solutions. Alternatively, the Examiner asserts that the pH is Badylak is within the claimed range; see MPEP 2112 which is incorporated herein by reference.

Claims 27-30, 34-36, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak (US 5,372,821) alone. Badylak discloses a submucosal tissue source which is first delaminated into tunica muscularis and tunica mucusa (i.e. submucosal tissue) prior to being disinfected because the material is obtained from the same method as set forth in Badylak's earlier patents of US 4,902,508 or US 4,956,178; see column 1, line 55 to column 2, line 15 and column 5, lines 64-68. The graft obtained can be sterilized by peracetic acid solution sterilization; see column 7, lines 21-33. The present claim language requires a step of separation after the disinfectant treatment rather than before as Badylak discloses. However, the Examiner posits that it would have been obvious to disinfect the tissue both before and after the delamination step as a precaution in order to better ensure sterility of the final implantable product. Furthermore, there is no criticality disclosed in the present specification that shows that it is important to sterilize before delamination. Applicants have not disclosed that changing disinfecting the tissue prior to delamination provides some advantage, is done for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' method to perform equally well because it would result in a submucosal tissue which has been treated with a disinfectant.

Therefore, it would have been an obvious matter of design choice to modify Badylak's method to obtain the invention as specified in the claims.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
Primary Examiner
Art Unit 3738